



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-604/S-027

Serono, Inc.
Attention: Pamela Williamson Joyce
Vice President, Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Joyce:

Please refer to your supplemental new drug application dated October 31, 2002, received November 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serostim [somatropin (rDNA origin) for injection].

We acknowledge receipt of your submissions dated January 29, February 7, June 10, August 12, 19, 28 and 29, 2003.

This supplemental new drug application provides for the use of Serostim [somatropin (rDNA origin) for injection] for HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed submitted August 29, 2003.

Please submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format-NDAs". Alternatively, you may submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-604/S-027." Approval of this submission by FDA is not required before the labeling is used.

We approved this NDA under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 314.510.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must submit, as correspondence to this application with the designation of “Patent Information-FDA Form 3452”, patent information on FDA Form 3542, Patent Information Submitted Upon and After Approval of a NDA or Supplement, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2). The form may be obtained at www.fda.gov/opacom/morechoices/fdaforms/cder/html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research “Orange Book” staff at

Food and Drug Administration
Office of Generic Drug, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20575-2773

We also remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center of Drug Evaluation and Research

Enclosure: Draft Labeling

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Orloff

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